Remarks

Applicants would like to thank Examiner for having an interview with Mr. Baran and Mr. Johnson regarding this case on August 9, 2005.

Claims 26 and 27 are added as intermediate claims as suggested by Examiner in the August 9, 2005 interview. Support for the corticosteroid limitation is provided in the specification p. 10, line 24.

35 U.S.C. § 103

As discussed in the interview. Applicants particularly point out that Figures 2-4 and Example 2, beginning on p. 21 show that the present method is effective in delivering therapeutically active agents to the back of the eye. In particular, Applicants refer to Figure 4 and Table 2, which succinctly highlight the advantages of the present composition and method. As shown in Table 2, compositions 2a-2f all contain a cyclodextrin, while 2g does not. There is a significant barrier between the aqueous humor (AH) and vitreous humor (VH). For example, formulation 2g, which contains no cyclodextrin, provides a significant concentration of prednisolone to the aqueous humor, but is unable to deliver prednisolone from the aqueous humor to the vitreous humor. By contrast, all of the formulations with a cyclodextrin were able to deliver a significant amount of prednisolone through the barrier. Each of compositions 2a-2g was administered topically. Thus, the cyclodextrin has the unexpected and previously unknown property of being able to deliver a drug from the aqueous humor to the vitreous humor and facilitating delivery to the back of the eye via topical administration.

This is a significant contribution to the art because at the time the application was filed, topical administration was generally ineffective, and delivery of drugs to the back of the eye was generally accomplished by injection into the eye or implantation of a drug delivery device. Thus, the present compositions and methods avoid the undesirable and unpleasant necessity of cutting or inserting sharp objects into the eye.

Applicants also submit herewith an Supplemental Information Disclosure Statement with a new study that has come to their attention recently. In this study, the prednisolone concentration was measured 6-9 hours post dose, and no drug was detected. By contrast, the study described in the specification sampled 1 hour post dose. Thus, it appears that the drug is completely eliminated some time between 1 hour and 6-9 hours post dose, but this does not adversely affect the original conclusion that the claimed method delivers the drug to the back of the eye.

In light of the amendments and the arguments made herein. Applicants believe that the claims are patentable as they now stand, and respectfully request that Examiner remove the rejections and allow the application to pass to issue.

Please use Deposit Account 01-0885 for extension of time fees or any other fees or credits relating to this response.

Respectfully submitted,

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CERTIFICATE OF FAX TRANSMISSION
I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING TRANSMITTED TO THE CENTRAL FAX NUMBER 571-273-8300, ON 8/19/05. 2005 (Date) Name of person making deposit:
Bonnie Ferguson
Signature: Bonnie Ferguson Date 8/19/05